Environmental Research Division

Quality Assurance Plan

May 2004

APPROVED:

Barry M. Lesht
Acting Director
Environmental Research Division

Contents

1 Introduction

The Environmental Research (ER) Division reports to the Associate Laboratory Director (ALD) for Energy and Environmental Science and Technology (EEST). The mission of the ER Division is as follows:

> The mission of the Division is to conduct forefront multidisciplinary research, both in the laboratory and in the field, to advance our knowledge of natural processes and to better understand and mitigate the effects of human activities on the environment.

The goal of the ER Division is to develop programs and associated staff that are supportive of this mission and will lead to the recognition of the Division as a major resource for environmental research. Fundamental to achieving this goal are an environment within the Division that supports quality research and a staff with a commitment to the highest standards of quality. Adherence to the *Quality Assurance Program Plan (QAPP)* of Argonne National Laboratory is a major key to successfully reaching this goal. The *QAPP* implements the requirements of DOE O 414.1A ("Quality Assurance").

2 Definitions of Terms and Notation

2.1 Definitions of Terms

Terms used in this document are defined as indicated below.

Activity: Any task or operation that may affect quality; sometimes referred to as a quality-affecting activity.

Applied research: Research and development activities having specific goals and goal-related funding, involving expansion or application of knowledge available to science.

Assessment and verification: The act of reviewing, inspecting, testing, checking, conducting surveillance, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. As an integral part of a work process, verification is conducted by or for the organization performing the work but not by the person who performed the work. Assessment is generally performed by or for management to periodically evaluate performance with regard to requirements and the achievement of goals and objectives for quality.

Basic research: Research activities having the goal of producing knowledge new to science.

Certification: The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, or items, in accordance with specified requirements.

Control: A practice that regulates an action or directs an activity in order to facilitate a consistent and predictable outcome.

Criterion: One of the ten areas of management concern on which this manual is based.

Critical material: Material that, if damaged, could cause significant programmatic delay, could jeopardize the operation or safety of a facility or experiment, or could allow significant release of chemicals or radioactivity or create other undesirable conditions.

Document: Issued material recorded on paper or machine-readable or other physical media that (1) describes, specifies, reports, certifies, provides results, or otherwise furnishes information or (2) defines policies, practices, procedures, or requirements.

Experiment: A test or investigation performed in a laboratory, operating facility, or field site for the purpose of meeting programmatic objectives.

Goals: See mission, goals, and objectives.

Graded approach: The formality with which requirements are implemented, based on the hazard and the potential consequences if that hazard is not mitigated.

Hazardous material: Material that is known to cause biological or physical damage to the user or the environment (e.g., radioactive materials, fissile materials, certain chemicals).

Inspection: The verification function of examining, measuring, or testing to obtain data to determine whether an item or process conforms with specified requirements.

Item: In the context of the Laboratory's quality assurance program, "item" is an all-inclusive term used in place of any of the following: documented concepts or data, sample, material, component, assembly, subassembly, module, equipment, part, system, subsystem, unit, structure, facility, or appurtenance.

Line management: The chain of authority and responsibility in any branch of the Laboratory organizational structure, originating with the Laboratory Director and extending unambiguously to individual employees. The term should not be confused with the categorization of "line" and "support" organizations at the Laboratory, which conduct research programs or provide support functions, respectively.

Manager: The head of an organization or a person with technical management responsibility.

Metrication: An activity that increases the use of the International System of Units (SI), including training and the initiation or conversion to the metric system of new or existing measurement-sensitive processes, software or hardware systems, and engineering standards.

Mission, goals, and objectives: In the context of this *Quality Assurance Plan (QA Plan)*, the series mission —> goals —> objectives represents a continuum of diminishing scope and increasing specificity and time dependence. These three programmatic elements, along with externally and internally defined expectations and specifications, are achieved by meeting performance requirements.

Nonconformance: A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity indeterminate or unacceptable.

Objective: See mission, goals, and objectives.

Organizational unit: A division, program, office, department, section, project, or other organized entity that functions as a unit and has common mission and goals and similar risks and operational characteristics.

Peer: An individual with widely recognized expertise and judgment in a particular field. Generally, such a person has an education in an appropriate technical discipline, a level of academic education equivalent to those performing the work, an established record of technical achievement, and an awareness of current progress in the research field under evaluation.

Peer review: A documented process whereby the quality and validity of technical work are evaluated by technical peers who did not participate directly in the work being evaluated. Peer reviews may be used during all phases of the scientific/engineering process.

Procedure: A prescribed set of instructions, usually written and implemented in a prescribed sequence.

Process: A series of actions that achieve an end or result.

Quality: The degree to which an item, research activity, or process meets or exceeds the internal or external user's requirements and expectations.

Quality affecting: Personnel, activities, or items that can affect the ability to meet a requirement.

Quality assurance: Those actions that, when carried out, provide confidence that quality is achieved.

Quality assurance program: (1) The overall Laboratory program established to implement the requirements of DOE O 414.1A. (2) An organization-specific quality assurance program that implements the requirements of this *QA Plan*.

Quality assurance records: Records providing evidence that requirements are met or that quality assurance provisions are indicated or completed.

Records: Papers, books, notebooks, photographs, reports, drawings, specifications, machine-readable materials, or other documentary materials that, regardless of physical form, preserve evidence of policies, decisions, procedures, results, operations, organizations, functions, conformance, or activities.

Responsibility: An assumed obligation with granted authority that requires an individual or group to be accountable for the outcome of an event.

Requirements: The tasks or provisions of a project that are so crucial to meeting the project's goals that, if their performance does not meet expectations, the task must be redone or the material object replaced.

Risk: A qualitative or quantitative expression of possible loss that considers both the consequences of an undesired event and the probability that the event will occur. Risk applies to (1) the organizational mission, goals, objectives, and performance requirements and (2) environmental protection, health, and safety. The degree of risk helps determine the level of formality and rigor with which appropriate quality assurance actions are implemented.

Sensitive item: Items such as computer equipment, software packages, and other expensive, confidential, or proprietary articles that can be stolen or destroyed.

Software: Computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system.

Test: The verification function or the determination of the capability of an item or process to meet specified requirements by subjecting it to physical, chemical, environmental, or operating conditions.

Validation: An activity that demonstrates that an item or process will perform under conditions of actual use and satisfy the requirements of the end user.

Verification: See assessment and verification.

Work, work process: Work processes in the Division are diverse in type and scope. They can include, but are not limited to, research and development; data collection and analysis; software development and use; technical analysis; design, maintenance, and repair of equipment; inspection; safeguards; and administration.

2.2 Notation

The following notation is used throughout the text. In addition, "Laboratory" signifies Argonne National Laboratory, and "Division" signifies the ER Division.

ACL	Acceptance Criteria Listing
ALD	Associate Laboratory Director
AMOS	Argonne Materials Ordering System
DD	Division Director
DOE	Department of Energy
EEST	Energy and Environmental Science and Technology
ER	Environmental Research
ESH	environment, safety, and health
ESSH	environment, safety, security, and health
ESH/QA	Environment, Safety, and Health/Quality Assurance (as in Office of ESH/QA Oversight)
FWP	Field Work Proposal
IEEE	Institute of Electrical and Electronics Engineers
M&TE	measuring and testing equipment
MSDS	material safety data sheet
PD	position description
PI	principal investigator
QA Plan	*Quality Assurance Plan* (ER Division)
QA	quality assurance
QAPP	*Quality Assurance Program Plan* (Argonne)
QAR	Quality Assurance Representative
SHE	Safety, Health, and Environment (Committee) (ER Division)
SI	International System of Units
TMS	Training Management System

3 Policy

The policy of the ER Division is that all activities undertaken by Division personnel must be in compliance with all Laboratory policies and procedures, including the quality assurance (QA) policy and the *QAPP*. These activities must incorporate all reasonable measures to ensure that the Laboratory standards for quality are achieved. This policy applies to all Division activities, whether they are conducted on-site at the Laboratory, at a contractor's facilities, or at a remote field site. Quality assurance is a line responsibility, and such responsibility is automatically delegated when responsibility for performance of an activity is delegated. This policy requires that

- All research, development, and operational activities employ measures to achieve the required degree of quality while they simultaneously achieve effective safety and environmental protection for employees and the public;

- Testing services, calibrations, and computer-related activities (including computer software development) are performed in a manner that assures high technical quality; and

- Procurement and fabrication activities include a level of QA consistent with the requirements specified for each activity.

All activities must conform to the Division's *QA Plan*, but some activities have additional QA requirements because of their scope and complexity. For example, field projects need to reflect the effect of conditions at remote sites. Such activities must have supplemental QA amendments to this *QA Plan*, addressing all unique task-specific operations. A list of such amendments to this *QA Plan* will be maintained by the Quality Assurance Representative (QAR). Copies will be kept in the Division administrative office.

This policy recognizes that the basic QA requirements may not apply uniformly to each item, process, or activity and that they may vary depending on the associated risk. Therefore, a graded approach to QA is recognized, as defined in the Laboratory's *QAPP*.

This policy further recognizes that peer review is an additional QA instrument for the basic and applied research functions of the Division. Quality continues to be ensured by formal reviews by the University of Chicago, the Department of Energy (DOE), and other funding agencies and by external and internal peer review of manuscripts and proposals written by members of the Division.

The provisions of this *QA Plan* are implemented within the Division with the aid of a companion document, the *Quality Assurance Plan Implementation Guide*, also in this volume. The *Implementation Guide* is a dynamic document that is subject to revision as needed.

4 Quality Assurance Criteria

4.1 Management Criteria

4.1.1 Criterion 1 — Program

This *QA Plan* defines the quality management system that will facilitate the Division's efforts to address its mission successfully.

4.1.1.1 Organizational Structure

The Division's organization chart (Appendix A) shows the structure that has been developed to provide the resources and support necessary to conduct the diverse research programs undertaken by the Division.

4.1.1.2 Responsibilities

The responsibility matrix for QA criteria (Appendix B) identifies the individuals responsible for preparation, review, and approval of quality-assuring criteria. The various administrative units within the Division (procurement, budget, etc.) are responsible for assisting those with primary responsibility. Individuals responsible for and executing activities under this *QA Plan* may delegate any or all tasks to others, but they retain the responsibility for assuring the effectiveness of QA. Persons not directly responsible for performing a specific task may be called upon to verify that quality goals are achieved. The functional responsibilities of the individuals with primary responsibility for QA are specified below.

Division Director

The Division Director (DD) is responsible for the quality of all work conducted by the Division. In particular, the DD is responsible for the establishment of the organizational structure, functional responsibilities, levels of authority, interfaces, and lines of communication for all activities in the Division; for the establishment of the Division's QA policy; and for the preparation and effective implementation of the Division's *QA Plan*. In conformance with requirements of the Argonne *QAPP*, the DD will annually submit an assessment agenda to the Director of the Office of Environment, Safety, and Health/Quality Assurance (ESH/QA) Oversight.

Quality Assurance Representative

The Division QAR will (1) assist Division personnel in the development and implementation of task-specific *QA Plan* amendments, procedures, and training activities as needed; (2) maintain a list of task-specific amendments to this *QA Plan*; (3) review and assess quality-affecting activities; (4) assist in the identification of areas for quality improvement; (5) act as the Division's liaison with the Office of ESH/QA Oversight; (6) represent the Division in QA matters as directed by the DD; and (7) perform other activities in the area of QA as directed by the DD.

Principal Investigator

The principal investigator (PI) or, in large projects, the program manager, will establish detailed QA requirements and procedures for all activities affecting quality within the purview of the PI's activities. The PI will verify that such activities have been correctly performed and documented. For new and existing activities, the PI will develop the QA requirements and procedures by giving consideration to the following topics:

- The technical requirements for the work and the activities and items that can affect the ability to achieve these requirements. The latter are considered the quality-affecting activities and items, including processes; process parameters; designs; procedures; materials; systems; equipment items; computer codes; or sensitive, limited-life, or high-value items.

- The risks or consequences if the quality-affecting activities or items do not perform as expected. For example, the PI must evaluate the seriousness of the effects and of the risks and consequences of the attendant exposure of the Division or the Laboratory in case the identified activities or items fail, create unsafe conditions, or provide insupportable or unacceptable results. Specific consideration should be given to

  - Injury to project participants,

  - Injury to Laboratory personnel not involved in the project,

  - Injury to the public,

  - Negative effects on the reputation of the Division or the Laboratory,

  - Negative effects on the schedule of the project or other projects,

  - Negative effects on project status or costs, and

  - Negative effects on the reputation of the researcher.

The Division will take advantage of the resources and technical expertise within the Office of ESH/QA Oversight for assistance and coordination where needed.

Employees

All employees are responsible for the quality of their work. These responsibilities include understanding the requirements established for the work, meeting all training requirements, performing all work safely, and identifying and reporting problems or providing suggestions for improvement. In addition, all employees who find themselves engaged in an unsafe activity that they believe poses an immediate threat to themselves, the environment, or the safety and health of other employees or the public are empowered and obligated to stop the activity. An employee stopping work is obligated to immediately bring the hazardous condition to the attention of his or her immediate supervisor.

Safety, Health, and Environment Committee

The ER Division's Safety, Health, and Environment (SHE) Committee is a standing committee established by the DD to serve in an advisory capacity on matters relating to safety, health, and environmental protection. Members of the SHE Committee represent, to the extent possible, all major aspects of the Division's current experimental and investigative activities. The SHE Committee (1) reviews safety analyses prepared for new or significantly altered facilities and projects and (2) assists principal investigators in identifying and resolving safety, health, or environmental concerns associated with those facilities and activities.

4.1.1.3 Collaborative Activities

When a Division activity involves an organization outside the Division, whether internal or external to the Laboratory, the responsibility and authority of the Division must be clearly defined and documented. This documentation must specifically include descriptions of internal and external interfaces and the responsibility and authority of the Division with respect to areas affecting QA, such as inspection, assessment, verification, review, and approval.

4.1.1.4 Performance

Division activities are performed according to a graded approach, by using the guidelines in Table 1.

Table 1. Guidelines for a Graded Approach to Quality Assurance

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Potential for significant off-site impact or severe impact to the mission, with a delay of a year or more or possible cancellation.	Potential for significant on-site impact or delay of the mission by more than six months.	Potential for significant local impact, at most. This is the default level if no higher level is specified.

Division activities must be performed in compliance with the requirements of all Laboratory policies and procedures, contracts, research proposals, and similar documents. Measures for control and verification of performance will be planned, documented, and implemented. For research activities, the detailed proposal for peer review will be the basic document defining these activities. All research proposals are processed in accordance with the procedures required by the ALD for EEST. A review and evaluation form (Appendix C) is used to document the process. In the development of a proposal, all activities related to the research must be considered, and activities or items that would affect the validity of data or the ability to meet objectives, schedules, or cost or would ensure compliance with health, safety, and security requirements must be identified. The main planning document for DOE activities is the Field Work Proposal (FWP). The planning of all activities will include consideration of the following topics, as appropriate:

- Research and development objectives
- Assignment of responsibility for each activity or part thereof
- Review of drawings, specifications, and other working documents to ensure that prerequisites have been met and that quality-affecting activities can be accomplished as specified
- Quality requirements, including applicable codes, standards, and practices and the identification of all quality-affecting activities or items (those activities or items that can affect the ability to meet a requirement)
- Special procedures, instructions, processes, equipment, tools, or skills required to achieve quality results
- Acceptance criteria and inspection requirements for items produced by the Laboratory or a vendor
- Testing and measuring equipment, including calibration requirements, for achieving the required quality
- Special environment, safety, security, and health (ESSH) requirements
- Computer programming and software verification requirements
- Metrication requirements as specified by Laboratory policy
- Methods to assess conformance to requirements
- Documentation, such as certification and reports
- Program document filing, maintenance, and distribution
- Personnel requirements

Because of the nature of some activities, particularly those involving field studies or highly variable and evolutionary basic research, future activities may not be explicitly defined until a current activity has begun. In such cases the research is conducted in steps; changes may be required on the basis of the results of a previous step. These particular cases will be identified at their initiation, and special care will be taken to assure that adequate attention is given to quality, safety, and environmental requirements at each step.

The level of control and verification applied to a project will be based on the risk associated with the nature of the work; the need for compliance with environment, safety, health, and QA requirements; schedule; and cost. The risk associated with an activity will be appropriate for the objectives of the activity, the applicability of requirements, and the formality of implementation. The bases for grading the risk are the consequences and the probability of failure or error. The consequences of failure include harm to personnel, the public, and the environment; damage or loss of facilities, equipment, materials, or information; financial loss; invalid data; schedule problems; failure to meet commitments; and ineffective operation. The probability of failure may be objective (based on a quantitative ranking or probabilistic analysis), or it may be subjective (based on history and/or experience).

4.1.2 Criterion 2 — Personnel Qualifications and Training

All Division personnel must have the qualifications and training required to perform their assigned work with the proficiency needed to achieve the mission, goals, objectives, and performance requirements of the organizational unit.

Personnel qualifications and training will be evaluated according to a graded approach, by using the guidelines in Table 2.

Table 2. Guidelines for a Graded Approach to Personnel Qualifications and Training

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Formal procedures and training, qualifications, and/or certification are required.	Procedures may be semiformal (memos, operator aids, manufacturer's instructions). Suitable and appropriate training is to be provided.	Procedures may be informal or verbal. Other than basic orientation or awareness training, no other training might be necessary.

4.1.2.1 Personnel Qualifications

Personnel qualifications for each activity in the Division are defined in the position description (PD) for that activity. The PD includes a summary of the basic purpose of the position; typical activities; the work environment; required knowledge, skills, and experience; measures of effectiveness; decision-making authority; work relationships; work direction to others; and the financial dimensions of the position. The PDs for all staff members in the

Division are maintained by the DD. Position descriptions may be revised whenever revision is warranted; the opportunity to consider revision is provided at least annually.

4.1.2.2 Personnel Training

The policy of the Division is to advance the training of its staff through formal education, seminars, training programs, and participation in professional society activities and other activities considered to be of mutual benefit to the Division and the staff. Such training will allow each employee to perform his or her job in an efficient and effective manner and in compliance with existing regulations. All training activities must be documented, with records maintained in the Argonne Training Management System (TMS).

Support for formal education will be in accordance with the Division's Educational Assistance Policy. General programmatic training (e.g., project management, administration, and word processing) will be provided to individuals as needed. Training that addresses special needs of a program will be provided, when appropriate, to ensure that the employee understands the processes and tasks involved, the extent and sources of variability in those processes, and the degree to which the employee has control over the variability. Such training may include demonstrations of correct work performance, the necessity for quality requirements, problem recognition, and the potential consequences of improper work.

Each Division employee must complete the ESH training courses listed on the Employee Training Profile generated for him or her by the TMS on the basis of the employee's Job Hazard Questionnaire (reference *Human Resources Policy and Procedures Manual*, 5100.2, "Training Programs-Procedure"). Line managers, from the DD through and including PIs, must understand that certain ESH courses are operationally required. That is, these courses are of such a nature, either by law or by direct safety implication, that the training is absolutely required to perform a given function. The DD will identify such courses, prepare a list of those courses, distribute the list to all staff, and ensure that the training requirements are met. Formal ESH courses, or alternative means of training, must be completed before employees are permitted to work at these functions. The Division ESH Coordinator will maintain all ESH training records for the Division. In addition, QA training will be provided where necessary (for example, for the QAR). The QAR will provide the Division staff with formal and informal training.

4.1.3 Criterion 3 — Quality Improvement

Quality improvement is a line responsibility. Management at all levels will foster a "no-fault" environment, and the correction of quality problems will involve personnel at the lowest possible decision-making level. All personnel are encouraged to identify and report any unsafe working conditions and/or performance problems, along with suggestions for improvement, to their supervisor or to Division management so that corrective action can be taken. Abnormal conditions or problems, commonly called nonconformances, are deficiencies in characteristics, documentation, or procedures that render the quality of an item or activity unacceptable or

indeterminate, so that it will not meet requirements. Such nonconformance will be documented by using an ANL-E Quality Criteria Nonconformance Report form (ANL-626).

Quality improvement goals for individual activities will be established by the PI and discussed with the DD or with supervisors during program and performance reviews. These reviews will facilitate the analysis of recurring problems, identification of corrective actions, and communication of lessons learned to other segments of the Division.

The ER Division uses the web-based Sharepoint corrective action tracking system of Argonne's Office of ESH/QA Oversight to assure that actions taken to correct issues related to ER activities come to timely completion. The ER Division ESH Coordinator is responsible for monitoring the tracking system to ensure that necessary actions are completed and that lessons learned are transmitted to others where applicable.

4.1.4 Criterion 4 — Documents and Records

Documents and records will be reviewed, approved, distributed, maintained, used, and disposed of according to a graded approach, by using the guidelines in Table 3.

Table 3. Guidelines for a Graded Approach to Document and Record Control

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Formal, project-specific document control procedures are required for preparation, review, approval, distribution, use, and revision.	Established Laboratory policy and process for preparation, review, approval, distribution, use, and revision are to be followed.	May require no document or record control to assure quality.

The Division will comply with the requirements for records management specified in the Argonne *Policy Manual*, Chapter 6.16, and in the forthcoming Argonne *Records Management Manual*. In general, the records of a particular program, project, or task will be retained in the Division for five years after their completion; they will then be transferred to the Laboratory Records Management Program for maintenance and disposition, as appropriate. The ER Division Records Coordinator will be the point of contact with the Laboratory Records Management Program.

4.1.4.1 Programmatic Documents

For programmatic activities, the PI is responsible for ensuring that documents and records are created, maintained, and stored. The PI will identify documents requiring retention and will specify the procedures for their retention. In establishing any documentation or record system, consideration will be given to the purpose, retention period, reproducibility, and impact and probability of error or loss. Documentation might include laboratory notebooks; computer

software; data acquisition charts, tapes, disks, or other original media; design documents; project review documentation; descriptions of quality-affecting systems; purchase requisitions, service requests, and related documents; and project management plans.

4.1.4.2 Divisional Documents

For activities of the Division administration office, the DD will identify documents requiring retention and will specify the procedures for their retention. Such documents might include procurement records, financial records, personnel training records, QA reports, administrative correspondence, publications, and other documentation that may be pertinent to the operation of the Division.

4.1.4.3 Controlled Documents

Documents may be specified as controlled and approved for use by the DD (for documents affecting all or part of the Division staff) or by a PI (for documents affecting a specific activity). When a revision or other update of a controlled document is issued, the DD or PI, as appropriate, will advise each recipient to use only the current issue and destroy older versions. The date of the document will be updated to note the latest version. The DD or the PI, as appropriate, will be the only individual to maintain archival copies of controlled documents. Unless the DD or the PI, as appropriate, determines that the level of risk warrants a different frequency, documents controlled by the ER Division will be reviewed every two years. Examples of these documents include the *Environmental Research Division Safety, Health, and Environmental Protection Policy and Procedures Manual*; and the *Environmental Research Division Chemical Hygiene Plan*. The ER Division *QA Plan* will be reviewed and updated yearly if necessary, as required by the Argonne *QAPP*. The ER Division documents are online at http://www.anl.gov/ER/manuals.html.

4.2 Performance Criteria

4.2.1 Criterion 5 — Work Performance

Controls on work performance within the ER Division will be implemented according to a graded approach, by using the guidelines in Table 4.

Table 4. Guidelines for a Graded Approach to Controlling Work Performance

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Formal controls (e.g., assignments, plans, safety analyses), schedules and milestones, qualified personnel, progress reporting, verification and validation, and readiness reviews are necessary.	Semiformal controls (e.g., work plans and written memoranda of understanding), qualified personnel, and progress reporting are sufficient.	Procedures may be informal or verbal. Other than basic orientation or awareness training, no additional training might be needed.

Work performance is defined as activities, actions, or operations that involve personnel and/or materials in the conduct of laboratory or field experiments, creation of samples, development of computer software, performance of analyses, delivery of services, or generation of any other type of product. Activities that significantly affect the quality of the work produced must be clearly identified and documented. When feasible and practical, all work will be conducted by using the metric system (SI units), as required by Laboratory policy.

4.2.1.1 Personnel

Line management must provide documentation about the expectations, guidance, or specific procedures that are appropriate to a given activity. Personnel performing work must be knowledgeable about the requirements of the work. Management must also ensure that personnel are knowledgeable in their assigned tasks and are capable of performing these tasks, as well as that the performance of the tasks has produced results of the required quality.

The qualifications and training of personnel are addressed in Section 4.1.2. The core competency requirements and expectations are given in the PD. If special knowledge is required for the performance of work, the requirements must be specified in sufficient detail so that the scope of the task is completely understood by the worker. Written procedures for complex or hazardous work will be prepared when appropriate. Such requirements will be identified in planning documents for the program. The degree of specificity of instructions will be commensurate with the identified risk of failure or error.

The criteria for acceptable performance must be specified, and the annual performance evaluation of personnel must reflect the degree of acceptability. These criteria and the measures of effectiveness of performance are usually contained in the PD. Unacceptable performance may affect quality and should be discussed during the annual performance evaluation.

4.2.1.2 Materials and Processes

Materials and items that significantly affect quality must be identified and controlled to ensure their proper use; maintained to prevent their damage, loss, or deterioration; and properly handled, shipped, and received. Equipment used for data collection or for in-process monitoring

of work will provide output in metric (SI) units, whenever feasible and practical, and must be calibrated and maintained as required to achieve the specified performance requirements.

The principal work processes in the Division are scientific analysis and experimentation. These processes are addressed below.

Identification and Control of Items

When specified by programmatic requirements, procedures must be established to ensure that only correct and accepted materials and items are used in the conduct of work. Identification must be maintained either on the items or in documents traceable to the items. For example, quantities and locations of general chemical supplies and reagents are controlled by the Division's chemical inventory system; hazard communications associated with these chemicals are provided by material safety data sheets (MSDSs), which are online.

The *Environmental Research Division Chemical Hygiene Plan* ensures that adequate control methods are implemented to prevent unacceptable exposure to hazardous chemicals in laboratories. This plan applies to laboratory operations using hazardous chemicals in relatively small quantities.

Topics to be addressed regarding the identification and control of items will include the following, if appropriate:

- Identification or tagging of each item and its quality status
- Identification, verification, and documentation of construction or safety codes, standards, specifications, and material grade or heat number associated with each item
- The traceability of items, samples, and materials
- Inspection status of inspected items

The PI is responsible for assuring that all items used in a project or program are adequately identified and controlled, where necessary, and that appropriate records are maintained of the identification and control of quality-affecting items.

Handling, Storage, and Shipping

Instructions for adequate marking and labeling for handling, storage, and shipping of an item must be established as necessary to identify, maintain, and preserve the item. The presence of special environments or the need for special controls and safety or security precautions must be clearly identified. Standard and special tools and equipment will be used and controlled as required to ensure that their handling is safe. In addition, equipment and tools requiring special handling or involving particular risk or safety hazards will be inspected and tested to verify adequate maintenance in accordance with applicable procedures and at specified intervals.

Operators of special handling and lifting equipment must be experienced or trained in the use of such equipment.

The use of hoisting and rigging equipment in handling items associated with research activities in the Division is subject to requirements specified in the Argonne *ESH Manual*, Chapter 16.2, and the *Hoisting and Rigging Manual*. Both manuals are online. All users of hoisting and rigging equipment within the Division must receive proper training and obtain certification to match their use of such equipment. Records of training and certification will be maintained in the TMS.

Handling, storage, and shipping of items must be in conformance with established work, inspection, shipping, and safety instructions; drawings; specifications; and other documents or procedures specified for these activities. Procedures will be in accordance with the requirements specified in the *Environmental Research Division Safety, Health, and Environmental Protection Policy and Procedures Manual*; the *Environmental Research Division Chemical Hygiene Plan*; the Argonne *ESH Manual*; the Argonne *Waste Handling Procedures Manual*; and the *Special Materials User's Guide*. Hazardous materials, critical materials, sensitive items, special samples, perishable items, or radioactive materials must be handled, stored, and shipped in accordance with the *Hazardous Materials Transportation Safety Manual*.

Radiological Work

Radiological work in the Division consists of the use of naturally occurring and relict man-made radioisotopes as tracers of environmental processes. The analysis techniques may involve volumetric concentrations of environmental samples, but the processes used create no additional activity. The Division maintains low levels of radiological standard materials for calibration of the instruments used for these analyses. The total amount of radioactivity present in the combined standards is far below any limits requiring special radiological controls. Therefore, administrative control will be implemented at a level commensurate with the hazard.

Internal Dosimetry. Radiological workers in the Division will participate in the Laboratory's routine bioassay monitoring program. Participation includes compliance with requests for bioassay samples.

External Dosimetry. Radiological workers in the Division will participate in the Laboratory's personal dosimetry program. The organization administering this program will determine the type of dosimeter required for the level of work being performed; assign the personal dosimeter; and perform the required collection or exchange, processing, and interpretation of results from routine processing.

Radiation Safety Training. Radiological work in the Division is classified at or below the level that requires Radiation Worker I training. Required training for work with radioactive material will be determined on the basis of the employee's Job Hazard Questionnaire and through the Employee Training Profile subsequently generated by the TMS.

Posting of Controlled Areas. Posting for radiation protection will be by use of warning signs at the entrance to areas in which radiological work is performed. The posting will provide information on the radiological condition of the area and specify the requirements for entry. The information will be sufficiently clear to allow the reader to make an informed decision about whether to enter the posted area. A qualified health physicist will provide assistance in posting an area with appropriate warning labels and signs. Labeling of radiation controlled areas within the Division will conform with the Argonne *ESH Manual*, Chapter 5.25.

Labeling. Labels or tags will be placed on containers of radioactive materials, on an object that is contaminated, or on a radioactive source. Labeling of radiative materials within the Division will conform with the Argonne *ESH Manual*, Chapter 5.26.

Workplace Monitoring. The amounts of radionuclides used in experimental work or stored within the Division are small. No individual radionuclide exceeds the activity level that would require containment, nor does the sum of the entire Division inventory.

Routine Surveys. The PI, the ESH Coordinator, and a qualified health physicist will jointly determine the exact frequency of surveys and types of surveys to be performed.

Containment Requirements. The amounts of radionuclides used in experimental work or stored within the Division are small (i.e., less than 0.10 μCi). No individual radionuclide exceeds the activity level that would require containment, nor does the sum of the entire Division inventory.

Accountability and Control. Source custodians are responsible for accountability and control of sealed sources within the Division. The Division Sealed Source Inventory Database Coordinator is to ensure that the Division's inventory of accountable sealed sources is maintained.

Assessments. Informal quarterly assessments will be conducted by supervisors to ascertain that radiological controls are in place and are being used. Management assessments will be conducted at intervals determined by the DD.

Waste Management. Waste generators within the Division are responsible for documenting hazardous and special waste under the Resource Conservation and Recovery Act (RCRA), as described in the Argonne *Waste Handling Procedures Manual*, so that the waste can be properly disposed of by Waste Management (Plant Facilities and Services Division). All materials declared to be waste will be maintained in a safe, environmentally sound manner within the Division.

Calibration of Equipment

Tools, gauges, instruments, and other measuring and testing equipment (M&TE) used for activities affecting quality will be controlled and, at specified periods, calibrated and adjusted to maintain accuracy within required limits. The PI must identify quality-affecting M&TE that

requires calibration and control in order to ensure that the required precision and accuracy are achieved and documented, that reference standards are adhered to, and that prompt corrective action is initiated when M&TE performs outside specified calibration limits. Procedures will be established by the PI so that M&TE designated as quality affecting is controlled, calibrated, adjusted, and maintained by authorized and qualified personnel at prescribed intervals or before use. The basis for calibration must be documented, and traceability to national standards or a prescribed calibration standard is required. Records of calibration must be maintained, and equipment must be adequately marked to identify its current calibration status. In general, calibrations will fall into three general categories: (1) calibration done regularly by the researcher; (2) calibration done with each experiment through the use of standards as part of the data set; and (3) calibration covered in the manufacturer's contract. The calibration method must be clearly documented, including the calibration interval.

Calibration of some M&TE is handled under Argonne's contract with the manufacturer. Calibration of other M&TE is the responsibility of the PI for whose projects the equipment is used.

Analytical Work

Analytical efforts in the Division must be performed in a manner that will ensure high technical quality, relevance to identified needs, and a readily visible record of work planned and performed. Analytical work includes efforts that provide an understanding of the scientific principles necessary for the solution of a problem; result in a computer code to be used by persons other than the author or immediate collaborators; or require extensive interfacing of computer code modules, use of advanced data management techniques, or interfacing of technical disciplines in the analysis. When specified, analytical efforts will be planned. Planning will include a statement of goals and objectives, a statement of the expected product, and a schedule for completion.

Computer Modeling

A computer model is a numerical representation of a set of mathematical expressions whose solution describes the behavior of a physical process. A module consists of the code of one or more subroutines that together provide the numerical solution(s) to the equation sets of one or more processes. Validation of code modules and the code as a whole is part of the analytical effort. Validation can be accomplished by comparison of results generated by the module to (1) known analytical solutions to the equation sets solved in the module or a rational simplification of these sets, (2) results of other computer codes that model the same phenomena, (3) experimental results, or (4) the expected behavior of the processes simulated by the module. The results or output of all computer codes will be in metric (SI) units, whenever feasible and practical.

Before any code is released, documentation must be prepared that will enable an informed individual to make effective use of the code. At a minimum, the documentation will provide a

description of the equation sets and solution algorithms in the code, the organization of the code, and the input required by the code. The documentation must be prepared in accordance with the applicable standards for computer code documentation. All Division computer software must comply with the DOE N 203.1, "Software Quality Assurance," which is intended to assure that software and software initiatives are appropriately controlled and monitored through development, configuration, and inventory management and are in conformance with DOE and other federal requirements. The planning and development of any software should consider the requirements of the IEEE (Institute of Electrical and Electronics Engineers) "Standard for Software Quality Assurance Plans" (IEEE Std. 730-1998) and "Standard for Software Verification and Validation" (IEEE Std. 1012-1998).

Software

Software development in the Division is generally categorized at Quality Level C (Table 1), because the software is intended for scientific research and is thus overseen at the PI level. The PI is to assure that software development occurs in a planned manner and that the process is appropriately documented and traceable.

The following elements constitute the minimum documentation needed for software development categorized as Quality Level A:

- Requirements
- Roles and responsibilities
- Functional design
- System design
- Safety and security
- Training
- Procurement (if applicable)
- Configuration management
- Test plan, documentation, and results
- External review
- Verification and validation
- User documentation
- Implementation

Software development at Quality Level B or Quality Level C may use a subset of these elements, as appropriate.

All Division computer software must comply with DOE N 203.1, "Software Quality Assurance," and the Argonne software quality assurance policy, which are intended to assure that software and software initiatives are appropriately controlled and monitored. Management involvement may be necessary in procurement of off-the-shelf administrative software, especially as it may involve cyber security. The Associate Division Director serves as the Division Cyber Security Program representative.

Experimental Work

Experimental work in the Division must be performed in a way that provides an accurate record of the investigation. The objectives are to enable an independent evaluation of the results or independent duplication of the experiment with an expectation of obtaining similar results, to ensure the quality of results, and to ensure safety. All experimental activities will be conducted in the metric system with SI units, whenever feasible and practical. The requirements imposed on experimental work are not intended to abridge the spirit of experimental freedom or creativity.

All experimental activities are subject to the operating limits and conditions of the facility used for the experiment. The PI is responsible for developing an experimental plan that describes how and when an experiment is to be performed. The experimental plan may be documented in an FWP or other proposal. The plan may contain the following items, as appropriate:

- Test objectives
- Test requirements and conditions
- Design description and requirements
- Test operations plan
- Safety and security analysis
- Quality assurance
- Analyses
- Documentation
- Schedules
- Budget

When appropriate, operating procedures will be prepared that state the steps to be performed in the operation and conduct of the experiment. These procedures, at a minimum, will include the following:

- Checklists for starting up and shutting down equipment being used in the experiment, including emergency shutdown.
- Detailed instructions for the operation of the experimental apparatus and the performance of the experiment. (The manufacturer's operations instruction manual may be sufficient.)
- Directions for performing analyses.
- Sample data sheets or other directions for gathering data.

The operating procedures must describe any safeguards required when the apparatus is idle. The calibration of instrumentation will be reviewed to determine whether calibration is up to date and to provide for calibration of any new instruments. Each experimental process will be provided with a statement of analysis of the safety of the experiment. This statement will indicate that the experiment can be conducted without undue risk to the general public, operating personnel, the facility, or the environment.

All experimental work must be recorded in a suitable log to maintain a chronological history of significant events that affect the performance, operability, or safety of the experiment. Log books will be maintained as described in Section 4.1.4. The form and content of these records will be determined by the PI and may include, but are not limited to, the following:

- Date and time of entry
- Identity of experiment
- Experimental conditions
- System calibration
- Special characteristics being investigated
- Parameters being measured
- Failure observation
- Total accumulated operating time and duty cycles
- Discrepancies noted during the experiment
- Repair and maintenance record

- Pertinent, unusual, or questionable occurrences
- Modifications made during the experiment
- Reference to supporting information or documentation
- Signature of person making the entries

At the completion of each experimental program, a written report will be prepared describing the results of the experiment. The report may be in the form of a letter that provides the results to the research sponsor, an Argonne report or document, a peer-reviewed publication, or other appropriate document.

4.2.2 Criterion 6 — Design

All design activities must be performed with the level of QA and documentation required to ensure the adequacy and completeness of design information, so that the work performed will produce items that will perform as intended. All design activities will be conducted in the metric system (SI units) whenever feasible and practical. The level of detail in design documentation for major items is different from that of smaller activities, although the level of quality and safety will be maintained commensurate with the scope, complexity, and risk associated with each item. The PI has the responsibility to define the design measures and level of detail required for each task and to maintain all related documentation in accordance with Criterion 4 — Documents and Records (Section 4.1.4).

Design reviews will be conducted, as appropriate to the quality and complexity of the task, to assure the following:

- That the design criteria are adequate, reliable, and complete.
- That the design complies with the criteria.
- That the design can be fabricated, inspected, and tested.

Design activities within the ER Division will be performed according to a graded approach, by using the guidelines in Table 5.

Table 5. Guidelines for a Graded Approach to Design Activities

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Independent and internal design and safety reviews, professional drawings and as-built drawings, documentation of functional requirements, and Division Director approval are all required.	Design and safety reviews, detailed sketches, as-built drawings, and approval of group leader or higher-level manager are required.	Verbal instructions, informal review by the worker, approval by the worker or his/her supervisor per Division practice for the activity, and building manager approval (as necessary) are needed.

When required, because of the complexity of an item, the PI may prepare a design plan describing the design effort to be accomplished in terms of components and assemblies. Such a plan may include the following:

- Statement of design approach and criteria
- Assignment of design responsibility to an individual
- Lists of specifications, drawings, analyses, and other documents to be prepared
- Lists of codes, standards, and QA and ESH requirements
- Design reviews
- Design schedule

In preparing the design criteria, the PI will consider the following characteristics for the item being designed:

- Functional requirements and design margin
- Operational environment
- Space and weight limitations
- ESH requirements
- Maintainability
- Handling, storage, and shipping
- Design life
- Reliability

- QA requirements

Design reviews will be conducted, as appropriate to the quality and complexity of the task, in order to assure the following:

- That the design criteria are adequate, reliable, and complete
- That the design complies with the criteria
- That the design can be fabricated, inspected, and tested

For research activities, the detailed proposal for peer review will be the basic document defining project plans and objectives, procedures, organizational interfaces, and assigned responsibilities. The detailed proposal must satisfy the requirements of this criterion. Because of the nature of some activities, particularly those that involve field studies or basic research, the design may not be explicitly defined until an activity has begun. In such cases the research and design are conducted in steps, with changes based on the results from a previous step. These particular cases will be identified at their initiation, and special care will be taken to assure that adequate attention is given to ESH and QA requirements at each step.

Some research projects within the Division involve the design and development of computer software. Such software design and development will be performed in an organized and planned manner. The methodology used will be appropriate to the software. Because software development is an evolutionary process, careful planning is necessary to assure that the deliverable item corresponds to the user's requirements.

The primary responsibility for design review, approval, concurrence, or change follows the designated management line. When required by the complexity of the design, special reviews will be conducted by qualified individuals other than those who performed the work.

4.2.3 Criterion 7 — Procurement

The procurement of quality-affecting items and services must conform to applicable Laboratory, DOE, and federal requirements commensurate with their complexity, risk, quantity, and programmatic significance. The procurement and receipt of equipment, materials, chemicals, and radioactive substances having the potential for introducing hazards will be reviewed by the ESH Coordinator to ensure that appropriate controls are in place and to comply with requirements delineated in Chapter 5.12 of the Argonne *ESH Manual* and the *Special Materials User's Guide*. Procurement activities within the ER Division will be performed according to a graded approach, by using the guidelines in Table 6.

Table 6. Guidelines for a Graded Approach to Procurement

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Technical specifications must be prepared, reviewed, and approved; acceptance criteria are to be listed (ANL-266); and quality assurance procurement requirements must be completed (ANL-407). Division Director approval is required, as is formal documentation of selection and approval of vendor.	Specific requirements beyond normal off-the-shelf specifications are established on the requisition. Acceptance criteria list (ANL-266) is to be completed. Division QAR review and signature are required.	Procurement involves commercial, off-the-shelf items or items obtained through the Argonne Materials Ordering System (AMOS). Manufacturer's warranty and catalog specifications and descriptions are sufficient for quality assurance.

The metric (SI) system will be specified in all procurement documents, whenever feasible and practical. As appropriate, the guidelines and procedures described in the *Procurement Operations Manual* will be used for procurement activities such as source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion. This procedure applies to requisitions for items and services from Laboratory organizations and outside vendors.

The PI is responsible for the review of requisitions, the assignment of appropriate quality levels, and approval of requisitions for all quality-affecting items and services. Applicable design bases and other requirements to assure adequate quality must be included or referenced in the procurement documents, including requirements to assure quality. Applicable codes and standards must be specified. Statements of work and technical specifications will be prepared, when necessary, in accordance with the *Procurement Operations Manual.* An Acceptance Criteria Listing (ACL; form ANL-266) will be used, when necessary, to specify the quality verification measures required to ensure product acceptability. If this form is used, the appropriate box ["Receiving Inspection/Test. ACL (ANL-266) Issued"] should be checked on the Purchase Requisition form (ANL-451). The PI then has the following three options:

1. Note on the ACL if someone other than the PI is to perform the inspection/test.

2. Note on the ACL if the PI is to perform the inspection/test upon delivery.

3. Attach to the requisition a list of requirements/specifications to be met. The following statement should be written in the box marked "Miscellaneous Notes": *Requester will verify that each requirement of the order is met, and the requester will retain records of verification, nonconformances (if any), and corrective actions for nonconformances*.

Upon receipt of the order, the PI will perform the inspections and note on the specification sheet that the requirements have been verified or note nonconformances and corrective actions. The requester will initial the form, which then will become the QA document.

Other Laboratory controls that are available to assure the quality of an item or service will be used throughout the procurement process as needed. These controls include (1) the Argonne Quality Assurance Procurement Requirements form (ANL-407), which enables the requester to use a graded approach and select from many options to ensure that quality requirements are achieved, and (2) the Report of Nonconformance form (ANL-267).

Procurement documents and associated records will be maintained in the Division administrative office. Additional records may be retained by the PI, as appropriate.

4.2.4 Criterion 8 — Inspection and Testing

Inspection and testing requirements within the ER Division will be applied according to a graded approach, by using the guidelines in Table 7.

Table 7. Guidelines for a Graded Approach to Inspection and Testing

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Formal acceptance testing is required. Inspection is to be per ANL-266 and ANL-407 by qualified personnel, in accordance with specified standards. Verification and validation plans are to be documented and reviewed by the Division QAR. Inspection plan and schedule must be developed, implemented, and reviewed periodically by line management and the QAR.	Acceptance testing may be formal or informal, as appropriate. General inspection is to be conducted by the requester and the Division QAR, with the support of specified qualified personnel, if necessary.	Acceptance testing is informal. Functional and quantity inspection is to be conducted by requestor upon receipt.

Inspection and testing requirements to verify the conformance of quality-affecting items or services to specified criteria will be planned and executed as appropriate for the complexity and risk associated with the performance of the item or service. The PI is responsible for the establishment and documentation of these requirements. Performance criteria may be documented, when appropriate, through the use of the ACL form (ANL-266) or the Quality Assurance Procurement Requirements form (ANL-407).

Inspection and testing must be performed by qualified persons. When appropriate, such inspection and testing will be conducted by persons who are not directly involved with the work performed. All inspection and testing will be conducted in accordance with written instructions or standard practices, by using calibrated M&TE.

The status of inspection and testing activities must be identified either on the items or in documents traceable to the items when it is necessary to assure that required inspections and tests are performed and to assure that items that have not passed the required inspections or tests are not inadvertently installed, used, or operated. Nonconforming items must be reviewed

by the PI to determine their disposition. Such nonconforming items must be discarded, returned to the vendor, or otherwise controlled by segregation or tagging to prevent their inadvertent use. Identification of nonconforming items must be legible and must not affect the end use of the item. Personnel who are responsible for evaluating nonconforming items to determine their disposition must have demonstrated technical competence, cognizance of technical requirements, and access to relevant background information. Justification of the acceptability of nonconforming items and their disposition (for example, to repair or use as is) must be documented with a clear identification of the degree of deviation from the requirements and its impact on performance, and the documentation must be retained as specified in Section 4.1.4. Repaired items must be inspected and tested in the same manner as the original item. Nonconformances that could be applicable to other Argonne organizations must be reported to the Office of ESH/QA Oversight. Nonconformances that could result in contractual actions or could affect the future consideration of vendors' qualifications must be reported to the Procurement Office.

4.3 Assessment Criteria

4.3.1 Criterion 9 — Management Assessment

Management assessments will be performed by Division management according to a graded approach, by using the guidelines in Table 8.

An assessment of all Division, project, and program activities must be conducted annually by Division management or the responsible PI. The purpose will be to evaluate achievement relative to performance requirements and to appropriately validate or update performance requirements and actions, in order to provide confidence that the quality goals are being achieved. The management assessment process will also periodically include an evaluation of the effectiveness of this *QA Plan* in fulfilling the Division's mission.

To complement the annual assessment, an Experiment Safety Review (Project Safety Analysis) is performed by the ER Division Safety, Health, and Environment Committee to assess the potential hazard level of each new or modified facility, operation, and experiment. This processes uses a graded approach.

Table 8. Guidelines for a Graded Approach to Management Assessment

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Assessments are to be planned, scheduled, and implemented, and the plan is to be documented. The periodicity will be clearly specified in the *QA Plan*, project plans, or other documentation. The depth of coverage should be sufficient to assure that all potential hazards are being safety controlled. Assessment teams must have the full complement of expertise to review all hazards at the facility and their release mechanisms. Corrective actions must be formally identified, implemented, and tracked. The Director, ESH/QA Oversight, is to receive copies of the corrective actions.	Assessments are to be planned, scheduled, and implemented. The team members must cover the technical aspects of the subjects being assessed. Assessment corrective actions must be formally identified, implemented, and tracked to completion by using organizational tracking systems.	The assessment may be less formal (e.g., simple walk-throughs), and the topics of coverage may be fewer than at higher-hazard facilities. Assessment corrective actions must be formally identified, implemented, and tracked to completion by using organizational tracking systems.

Overall performance indicators for the Division include the following:

- Safety of operations
- Status of training
- Opening of new areas of inquiry
- Recognition from the scientific and technical communities

In addition to these performance indictors, many of the individual sponsors have defined project- and program-specific performance requirements and expectations that are addressed through regular reviews, inspections, and audits of program- and project-specific procedures, documents, and records.

When the performance in a particular area is found not to satisfy the expected and acceptable performance standards, Division management will, in conjunction with the cognizant PI, determine the cause of the lack of performance, identify the corrective action to improve performance, and then evaluate the effectiveness of the recommended actions. Management assessments will be conducted periodically or when considered necessary by the cognizant PI or Division management. These assessments will be performed to inform Division management of the effectiveness of the implementation of this *QA Plan* and will identify activities where the quality of work needs improvement. Safety assessments will be conducted periodically as prescribed by the DD to determine the condition of the facilities and equipment, ESH compliance, and compliance with the requirements of the *Environmental Research Division Safety, Health, and Environmental Protection Policy and Procedures Manual*.

An assessment plan will be developed annually and delivered to the Director of the Office of ESH/QA Oversight. Assessments will be documented. Assessment results will be transmitted to the Director of the Office of ESH/QA Oversight, as well as to other organizations as "lessons learned," if applicable.

Management assessment reports, responses to assessment reports, corrective action reports, and follow-up reports must be retained as specified in Section 4.1.4 and reported to the EEST ALD and the Director of the Office of ESH/QA Oversight. The DD is responsible for the review of all assessment reports and the review and approval of corrective actions initiated by a PI. The PI is responsible for initiating periodic assessments of activities, implementing appropriate corrective actions on the basis of findings and observations, issuing assessment reports, and retaining the assessment reports as quality records.

Management self-assessment walk-throughs will be conducted by the DD, the ESH Coordinator, and other subject matter experts as required, to allow for real-time interactions and observations at the working level. These walk-throughs will enable management to evaluate

- The knowledge and skills of personnel;
- The quality of work being performed;
- The adequacy of and compliance with organizational procedures and ESH practices; and
- The state and status of facilities and areas, including material conditions, building maintenance conditions, and housekeeping practices.

Corrective actions for items of concern noted during walk-throughs will be documented if the concerns cannot be corrected immediately. Corrective actions will be tracked by using the web-based Sharepoint corrective action tracking system of Argonne's Office of ESH/QA Oversight.

4.3.2 Criterion 10 — Independent Assessment

4.3.2.1 General Assessment Activities

Independent assessments of ER Division activities will be planned and conducted at least once every three years. These assessments will be conducted according to a graded approach, by using the guidelines in Table 9.

Independent assessment activities will not be conducted by persons responsible for or involved in the work being assessed. The DD, with assistance of the QAR, is responsible for coordinating assessments of the Division's activities. The results of these assessments will be provided to the EEST ALD and to the Director of the Office of ESH/QA Oversight, as required in the *QAPP*.

Table 9. Guidelines for a Graded Approach to Independent Assessments

High Consequences — Quality Level A	Moderate Consequences — Quality Level B	Low Consequences — Quality Level C
Assessments are to be planned, scheduled, and implemented, and the plan is to be documented. The periodicity will be clearly specified in the *QA Plan*, project plans, or other documentation. The depth of coverage should be sufficient to assure that all potential hazards are being safety controlled. Assessment teams must have the full complement of expertise to review all hazards at the facility and their release mechanisms. Corrective actions must be formally identified, implemented, and tracked. The Director, ESH/QA Oversight, is to receive copies of the corrective actions.	Assessments are to be planned, scheduled, and implemented. The team members must cover the technical aspects of the subjects being assessed. Assessment corrective actions must be formally identified, implemented, and tracked to completion by using organizational tracking systems.	The assessment may be less formal (e.g., simple walk-throughs), and the topics of coverage may be fewer than at higher-hazard facilities. Assessment corrective actions must be formally identified, implemented, and tracked to completion by using organizational tracking systems.

If the results of an assessment identify deficiencies, the PI must identify, prioritize, and implement corrective actions. Actions taken to resolve assessment results must be documented, tracked, and reported to the DD. The DD will inform the EEST ALD and the Director of the Office of ESH/QA Oversight about the completion of corrective actions.

4.3.2.2 Programmatic Review

The programmatic performance of the Division is assessed primarily by the University of Chicago Review committee. The review committee evaluates the following:

- The quality of the staff and its performance during the review period
- The quality and timeliness of the programs
- The relevance of the work to the long-range goals of the Laboratory and the missions of the sponsoring agencies

4.3.2.3 Peer Review

The Division recognizes that peer review is the highest element of independent assessment to assure the quality of research. Peer review may be used during all phases of the scientific/engineering process, including review of research proposals, review of work in progress, review of results prepared for publication in professional journals, and review and evaluation of programs for both quality and adherence to missions, goals, and objectives. A periodic review of the Division's activities is conducted by a committee from the University of Chicago.

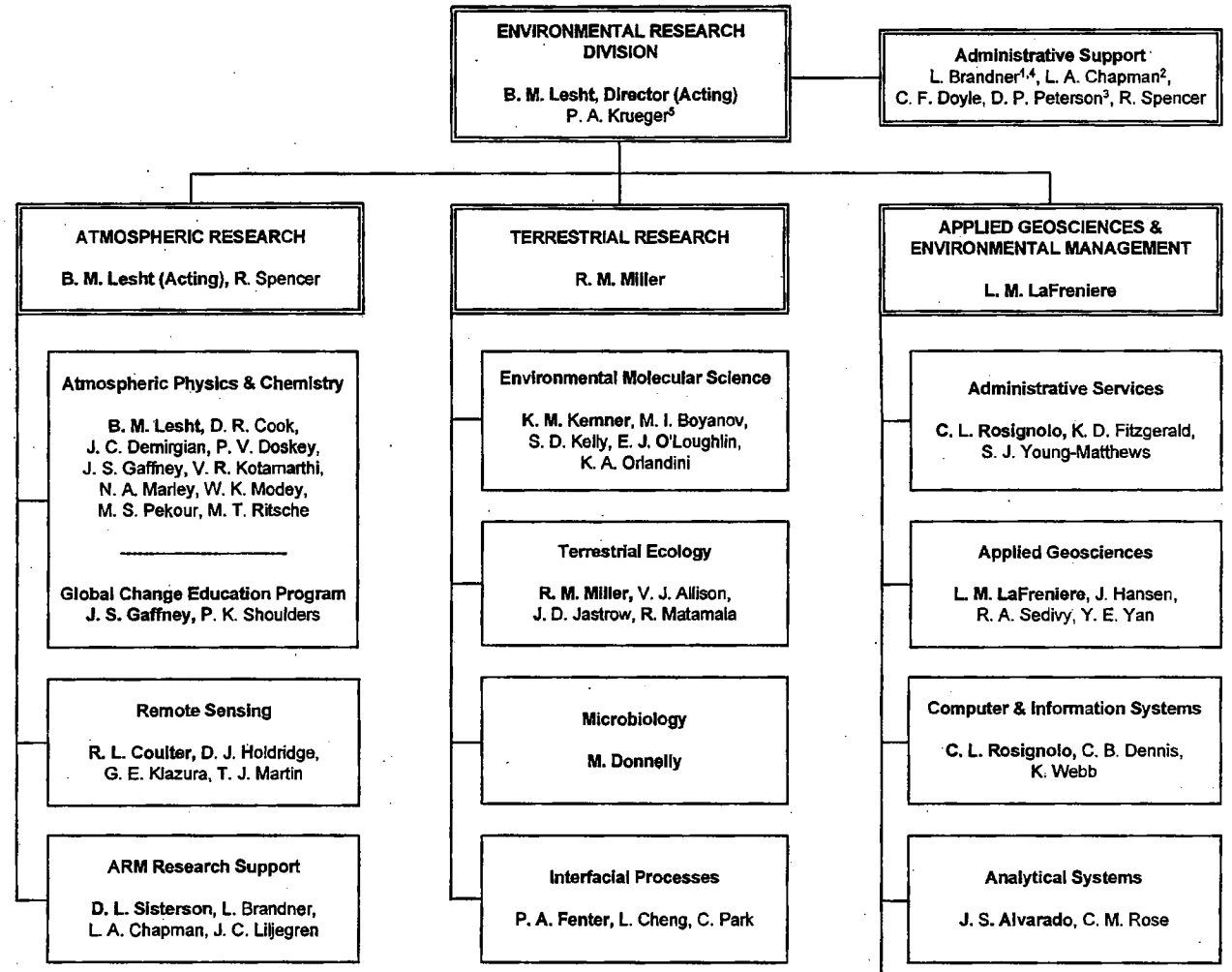
As shown in the document review matrix (Appendix D), the Division requires two peer reviews for journal articles, conference papers, books, book chapters, published reports, and proposals other than FWPs. Editorial reviews are also required for all of these and for FWPs. Reviewer comments may be written or verbal; revised documents may be resubmitted to the reviewer depending on the guidelines established by the PI or by management. Reviews of reports to a sponsor are dependent on guidelines established by the PI. Editorial review and peer review must be completed before any publication is released.

In addition to the above internal review requirements, publications may also be subjected to external peer review in accordance with the policies and procedures of various journals, organizations, or institutions to which the publications are submitted.

4.3.2.4 Incident Investigations

When deemed necessary by the DD, the director or the Office of ESH/QA Oversight, or the Laboratory director, an incident investigation may be conducted so that corrective actions can be implemented to address issues at the local level, the organizational level, or the institutional level. The purposes of the incident investigation are to (1) determine what happened, (2) determine why the incident happened, and (3) correct the situation and prevent recurrence. The DD will participate in all investigations. Others will be appointed to the investigation team at a level commensurate with the actual and potential extent of the damage or injury associated with the incident. All investigation reports and documentation must be retained as specified in Section 4.1.4.

Appendix A:
Environmental Research Division Organization Chart



Safety, Health & Environment
[1]Alternate Area Emergency Supervisor (203)
[2]Quality Assurance Representative
[3]Environment, Health and Safety Coordinator
[4]Field Safety Coordinator
[5]ER ESH Training Coordinator

B. M. Lesht March 2, 2004

Appendix B:
Environmental Research Division
Responsibility Matrix for Quality Assurance Criteria

Appendix B:
Environmental Research Division
Responsibility Matrix for Quality Assurance Criteria

Criterion	Responsibility[a] of Individual[b]			
	DD	PI	QAR	ESH/QA
Division QA Policy	P/A		R	R
Division Organization	P/A			
Training	A	P	R	
Quality Improvement	A	P	R	
Documents and Records	A	P	R	
Work Processes	A	P	R	
Design		P/A	R	
Procurement		P/A	R	
Inspection and Testing		P/A	R	
Management Assessment	A	P	R	
Independent Assessment	R	R	R	

[a] Abbreviations for responsibilities:
A, Approval
P, Principal responsibility for preparation
R, Review

[b] Abbreviations for individuals:
DD, Division Director
PI, Principal Investigator
QAR, Quality Assurance Representative
ESH/QA, Office of Environment, Safety, and Health/Quality Assurance Oversight

Appendix C:
Environmental Research Division
Proposal Review and Evaluation Form

ER DIVISION PROPOSAL REVIEW AND EVALUATION FORM

Sponsor's full name and address: Date of Submission _____

Name _____
Address _____
_____
Telephone _____

Section 1: Identification

Proposal No. P- TTP No. CH- FWP No. _____

Check One:
_____ New Start
_____ Revision – Argonne account no. _____

Responsible ALD (check one):
_____ Drucker
_____ Rosner
_____ Sackett
_____ Gibson

Principal Investigator(s) _____
Title _____

Have you, the Principal Investigator, discussed with the sponsor any security concerns (i.e., for information that is Classified, Sensitive Unclassified, Official Use Only, etc…) for this project that need special protection?
____Yes ____No (Check one item below.)
____There are no such requirements.
____The requirements and an implementation plan have been defined/discussed.

Section 2: Scientific and Technical Review

a) A high degree of scientific and/or technical merit is reflected in the proposed work.
b) The professional qualifications of the staff are appropriate.
c) The facilities and equipment to be used are appropriate.
d) The performance schedule is realistic.

Reviewer Name	Date	Organizational Affiliation	Comments*

Section 3: Acceptance Review *(required only for work for others)*

a) Work involves significant innovative research, development, and analytical methods.
b) Work requires special ANL capabilities.
c) Project solves problems of high national priority.
d) ANL's lack of bias is a key component.
e) Core skills and special capabilities are of use to DOE.

EEST Special Assistant for WFOs	Date	Comments*

Section 4: Section Head/Group Leader Review

a) The staff, equipment, and facilities required for this research are available or can be acquired.
b) The management and reporting requirements of this work can be met with existing systems or by those proposed within.

Section Head/Group Leader	Date	Title	Comments*

ER DIVISION PROPOSAL REVIEW AND EVALUATION FORM (Cont.)

Section 5: Quality Assurance Review *(not required for preproposals or "short form" TTPs)*

Which type of quality assurance plan applies to this project?
_____ANL _____Division _____Program _____Project

Plan Name _____

_____

Quality Assurance
Representative (signature) _____ Date _____

Section 6: ES&H Certification *(not required for preproposals or "short form" TTPs)*

This project will be conducted in compliance with applicable federal and state regulations, DOE orders, and ANL policies and procedures for protection of the environment and the health and safety of employees and the public. The hazards associated with this project will be evaluated, and appropriate measures and procedures will be identified to eliminate, control, or mitigate the risks.

Principal Investigator (signature) _____ Date _____
ES&H/Safety Coordinator (signature) _____ Date _____

Section 7: Editorial Review

The proposal and supporting materials have been edited for stylistic consistency, spelling, and basic grammar, and the final copy has been proofread.

Editor	Date	Division	Comments*

Section 8: Budget Review

The proposed budget is consistent with the resource requirements and schedule, and reflects the appropriate charge rates.

Budget Administrator	Date	Organization	Comments*

Section 9: Management Review

a) The work is appropriate for a national laboratory.
b) The research is consistent with the policies and goals of the Laboratory.
c) The research involves no known conflicts of interest or other aspects that might be detrimental to the Laboratory, The University of Chicago, or the sponsor.

Cognizant Division and Program Directors	Date	Division/Program	Comments*

*Use an additional sheet for extended comments, if necessary.

SARS Applicability Assessment Form
Direct-Funded Programmatic Activities

Instructions: Fill out this form for each new funding proposal or for each proposal for continuing funding in which program content is altered sufficiently to significantly change the safety impact. A "significant change" would increase the hazard class of the work or of the facility or apparatus used for the work. When an individual proposal is part of a larger group of proposed activities or represents a change in a larger ongoing activity, the form may be prepared either for the individual proposal or for the larger group. If a group assessment is used, the individual proposals included must be clearly identified. Proposals submitted by users through their own institutions for work at ANL-E user facilities should not be addressed. This form should be completed by the technical personnel most knowledgeable about the hazards of the work and their accident implications (e.g., the principal investigator and the senior staff associated with the proposal). Upon completion, provide an independent review and approval of the form by the Division Director or his designee. File the completed form with the safety documentation for the proposal or with other safety documentation for the division.

A. Type of assessment (check the one that applies in each column):

_____ Individual proposal _____ New proposal
_____ Group of proposals _____ Significant change

B. Proposal/group identification (for a group assessment, provide the following information, as an attachment, for each proposal in the group):

Title _____

_____

B&R code or other proposal number _____
Principal investigator(s) _____

_____

Proposal date _____

C. Building(s) or facilities where conducted. If out of doors, indicate where, including off-site locations:

_____

_____

D. Determination of hazard class:

A preliminary hazard class of O is assigned if one or more of the following applies (check if appropriate):

_____ Involves the handling of nuclear weapons.
_____ Consists solely of construction-related activity.
_____ Work conducted primarily out of doors, e.g., observational environmental research, environmental characterization, environmental remediation. Exclusion assumes that NEPA documentation adequately addresses hazards.

A preliminary hazard class of C applies if the work is conducted in a facility or with apparatus covered by a safety analysis report. If applicable, indicate the name of the facility or apparatus:

_____

If a preliminary hazard class of 4 (low), 5 (moderate), or 6 (high) has already been assigned to this work but a safety analysis report has not been completed, indicate the reference (e.g., internal memo, letter to DOE) in which the hazard class is documented or attach the documentation.

_____

_____

Preliminary hazard class (check one):

_____ O Other – covered by other DOE Order requirements, as determined above.

_____ C Covered – involves a facility or apparatus covered by a safety analysis report.

_____ 1 Everyday routine – the potential hazards are routinely encountered and accepted in the course of everyday living by the vast majority of the general public.

_____ 2 Routine laboratory – the potential hazards found in the Laboratory R&D environment are considered routine and of minimal risk by the scientific community.

_____ 3 Nonroutine laboratory – potential hazards found in the Laboratory R&D environment involve specialized materials, energy sources, or equipment that might present limited and local on-site impact and negligible off-site impacts to people or the environment.

_____ 4 Low – the potential hazards might present minor on-site and negligible off-site impacts to people or the environment.

_____ 5 Moderate – the potential hazards might present considerable on-site impacts to people or the environment, but off-site impacts are minor at most.

_____ 6 High – the hazards have the potential for on-site or off-site impacts to large numbers of persons or for major impacts to the environment.

E. Supporting Information:

Provide any information about the nature of the proposal and its hazards, plausible accidents, or accident consequences that will help justify or clarify the hazard class. (Continue on additional pages if necessary.)

F. Depth and Detail of Safety Documentation:

Proposals falling into classes 4-6 require a safety analysis report. Proposals falling into class C are covered by an existing safety analysis report but may require supplemental safety documentation. Proposals falling into classes O or 1-3 require simpler safety documentation for the identification, characterization, and control of hazards and the reduction of accident risk.

G. Certification:

Prepared by: _____ **Date:** _____

Approved by: _____ **Date:** _____

Division Director or Designee

EEST APPROVAL FOR ENVIRONMENTAL EVALUATION

Release of Funds Is Contingent on Approval

A. DESCRIPTION (For consolidated approvals, attach continuation page.)

Name of project or activity _____

Division _____ Principal Investigator/Project Manager _____ (name)

Identifying number (enter all that apply):

_____ WFO proposal number _____ Work for Other DOE contractor

_____ CRADA proposal number _____ LDRD number

_____ FWP number _____ B&R Code

_____ Other (explain) _____

CONTINUE.

B. APPROVAL FOR OFFICE ACTIVITIES (If not applicable, GO TO Section C.)

The activity(s) described above will be wholly confined to conducting "office work" (e.g., program planning, management, and administration; information gathering; information/data analysis; preparation and dissemination of reports; modeling; conceptual design; software development).

For any off-site or on-site activities ANL personnel will not be responsible for directing or conducting: laboratory work, field sampling, geophysical or geological characterization, installation of field instruments, drilling or digging, or any other activities with potential for disturbing the existing ecological/environmental conditions.

Principal Investigator/Proj. Mgr. _____ (name) (signature) (date)

Environ. Compl. Rep. _____ (name) (signature) (date)

STOP if Section B is applicable.

C. APPROVAL FOR OTHER ACTIVITIES (Complete either item 1 or item 2.)

1. ____ As documented by completion of checklist EST-EE-02, the activities will fully conform with the criteria for a categorical exclusion for bench-scale research and development as described in EST-EE-03.

   The EST checklist (EST-EE-02) was completed on _____ (date)

2. ____ Other NEPA documentation has been approved by (check all that apply):

   _____ EST NEPA Owner _____ ANL NEPA Reviewer _____ DOE-Argonne

   Most recent approval _____ (date) (description)

EST NEPA Owner _____ (name) (signature) (date)

EEST CHECKLIST: CONFORMANCE WITH CATEGORICAL EXCLUSION FOR BENCH-SCALE R&D

For each line in sections 1, 2, and 3 enter either Y (yes), N (no), or NA (not applicable) with either (a) consultation of or (b) knowledge of the indicated sections of EEST-EE-03, "*Categorical Exclusion for Bench-Scale R&D: EST Criteria*."

1. "YES" is required for a categorical exclusion.

_____ All work will be conducted at ANL-E. (1)

2. "NO" is required for a categorical exclusion.

_____ 2.1 Construction or major renovation is required. (1)
_____ 2.2 A Safety Analysis Report is required. (2.1)
_____ 2.3 A new or modified RCRA or NPDES permit is required. (4.1)
_____ 2.4 A new or modified Federal/State permit is required. (4.5)
_____ 2.5 Asbestos removal is required as part of the R&D activity. (2.4)

3. "YES" or "NA" is required for a categorical exclusion.

_____ 3.1 Radioactive materials and sources of radiation will be used with appropriate control. (3.1)
_____ 3.2 Limited amounts of chemicals will be used appropriately. (2.2)
_____ 3.3 Limited amounts of PCBs will be used appropriately. (2.3)
_____ 3.4 Preparatory asbestos removal has been evaluated by PFS. (2.4)
_____ 3.5 Hazardous waste will be appropriately accumulated and disposed. (2.5)
_____ 3.6 Radioactive waste will be appropriately accumulated and disposed. (2.6)
_____ 3.7 Mixed waste will be appropriately accumulated and disposed. (2.7)
_____ 3.8 Studies of hazardous waste treatment will be preceded by notification of Illinois EPA. (4.5)
_____ 3.9 Noise protection will be provided. (3.2)
_____ 3.10 Emission of volatile chemicals will conform with existing permits. (4.2)
_____ 3.11 Emission of hazardous/toxic/criteria pollutants will conform with existing permits. (4.3)
_____ 3.12 Floor drains will be protected from hazardous/radioactive material. (4.4)

4. Description and Certification (Add continuation page for consolidated evaluations.)

Division _____ Name of project or activity _____

Identifying number (enter all that apply):

_____ WFO proposal number
_____ CRADA proposal number
_____ FWP number
_____ Other (explain) _____
_____ Work for Other DOE contractor
_____ LDRD number
_____ B&R Code

The responses in sections 1, 2, and 3 accurately represent the project or activity described in section 4. The project or activity will fully conform with the conditions in EEST-EE-03.

Principal Investigator/Proj. Mgr. _____
(name) (signature) (date)

Environ. Compl. Rep. _____
(name) (signature) (date)

EST-EE-01 (6/96)

Environmental Research Division Quality Assurance Review

A. Quality Assurance Plan Checklist

Project Title: _____

Principal Investigator(s): _____

_____

Sponsor: _____

Proposal Number: _____ ANL Account Number: _____

Period of Performance: _____

Key Personnel: _____

_____

Check each criterion in the Division *QA Plan* that applies to your research. Attach a brief justification for each excluded criterion.

	Criterion	Check	Reason for Exclusion (for criteria not checked)
1.	Program	x	
2.	Personnel Training and Qualifications	x	
3.	Quality Improvement	x	
4.	Documents and Records	x	
5.	Work Processes	x	
6.	Design		
7.	Procurement		
8.	Inspection and Acceptance Testing		
9.	Management Assessment	x	
10.	Independent Assessment	x	

B. Quality Assurance Planning and Implementation Review

For each of the ten QA criteria below, do the following:

- Mark (with an "x") the "ER Division Plan" column if the *Environmental Research Division Quality Assurance Plan* specifies adequate control.
- Mark (with an "x") the "Other Document" column if another existing document (aside from the *Environmental Research Division Quality Assurance Plan*) specifies adequate control. Identify the existing document on an appended page.
- Mark (with an "x") the "Amendment" column if project-specific amendment(s) must be prepared to specify adequate control. Define the new amendment(s) on an appended page.
- For QA criterion 6, 7, or 8, mark all three columns (with "NA") if the criterion does not apply to your activity (as established in the Quality Assurance Plan Checklist).

Quality Assurance Criterion	ER Division Plan	Other Document	Amendment
1. Program			
2. Personnel Training and Qualifications			
3. Quality Improvement			
4. Documents and Records			
5. Work Processes			
6. Design			
7. Procurement			
8. Inspection and Acceptance Testing			
9. Management Assessment			
10. Independent Assessment			

C. Quality Assurance Plan Summary and Certification

1. My review of the program requirements has revealed no quality-affecting activities or risks affecting compliance, health, safety, cost, or schedule that require a unique QA plan. The use of existing procedures described in the *Environmental Research Division Quality Assurance Plan* will provide the controls necessary to ensure satisfactory results.

Principal Investigator _____ Date _____

2. My review of the program requirements has revealed that certain quality-affecting activities require controls that are not contained in the *Environmental Research Division Quality Assurance Plan.* These additional requirements are identified and summarized on the attached sheet. I have checked the appropriate line below.

_____ Another existing document provides the needed control. The title of that document is:

_____

_____ It will be necessary to prepare detailed, written *QA Plan* amendment(s) for the proposed activity.

Principal Investigator _____ Date _____

Appendix D:
Document Review Matrix

TABLE 1 ER Division Requirements for Publications and Proposals (January 2004)

	Two Peer Reviews	Editing	Clearance	Budget Approval	QA Approval	ESH Approval	Division Signoff	EEST Signoff
Journal Articles	x	x	x				x	
Conference Papers	x	x	x				x	
Abstracts etc.		x	x				x	
Books and Book Chapters	x	x	x				x	
Published Reports	x	x	x				x	
Field Work Proposals		x		x	x	x	x	x
Other Proposals	x	x		x	x	x	x	x

Implementation Guide for the

Environmental Research Division

Quality Assurance Plan

May 2004

Contents

1 Introduction

The purpose of this guide is to assist Division personnel in the implementation of the Division's *Quality Assurance Plan*. Laboratory policy states that quality assurance (QA) is a line responsibility. Therefore, each principal investigator (PI) in the Division has the responsibility to ensure that a QA plan exists for each of his or her activities, that this plan is properly implemented, and that auditable records exist. In addition, a QA plan is required for each new proposal before it is submitted to a sponsor.

Because the requirements described in the Division's *QA Plan* are already part of the current administrative and research practices of the Division, the Division's *QA Plan* is adequate for most activities in the Division. However, amendments to the Division's *QA Plan* may be required for some activities. The Division has developed three forms that together will help a PI determine whether the Division's *QA Plan* is adequate for a given activity and will document this exercise in a form that is retrievable for audit. PIs must complete these three forms for each of their activities. In addition, task-specific *QA Plan* amendments must be created as needed. The three forms must also be completed before any new proposal is submitted for internal review.

2 Quality Assurance Plan Checklist

The Division's *QA Plan* has ten required QA criteria. Use the Quality Assurance Plan Checklist and the information given below to determine which of these criteria apply to your program or activity. Include a brief justification for excluded criteria in the space provided, or attach another sheet if needed.

Criterion 1 – Program. *Must be checked.* A QA program is required by DOE O 414.1A for each new and existing project or activity.

Criterion 2 – Personnel Training and Qualification. *Must be checked*. Management and PIs must ensure that personnel are qualified and trained to carry out their duties properly and safely.

Criterion 3 – Quality Improvement. *Must be checked.* Quality improvement is a line responsibility, and all personnel are to be involved in the correction of quality problems.

Criterion 4 – Documents and Records. *Must be checked.* Minimum documentation includes the research proposal or Field Work Proposal (FWP) and the three forms given in this *Implementation Guide*.

Criterion 5 – Work Processes. *Must be checked.* The acceptable level of personnel performance and performance indicators must be documented.

Criterion 6 – Design. Check if instructions, procedures, drawings, or documents that are critical to the quality of the work exist or must be prepared.

Criterion 7 – Procurement. Check if purchased items and services can affect the quality of work.

Criterion 8 – Inspection and Acceptance Testing. Check if quality-affecting items require inspection and/or testing. These include items that are procured, fabricated, assembled, constructed, or otherwise processed.

Criterion 9 – Management Assessment. *Must be checked.* Line management assessment of programs is required.

Criterion 10 – Independent Assessment. *Must be checked.* Independent assessment is required. It includes evaluations of technical, management, and ESH performance by organizations external to the Laboratory including DOE; other research sponsors; and various federal, state, and local agencies. It also includes the various levels of peer review required by the Division, the Laboratory, the University of Chicago, DOE, and outside agencies, including professional journals and other research sponsors.

Quality Assurance Plan Checklist

Project Title: _____
Principal Investigator(s): _____
_____
Sponsor: _____
Proposal Number: _____ ANL Account Number: _____
Period of Performance: _____
Key Personnel: _____
_____

Check each criterion in the Division *QA Plan* that applies to your research. Attach a brief justification for each excluded criterion.

	Criterion	Check	Reason for Exclusion (for criteria not checked)
1.	Program	x	
2.	Personnel Training and Qualifications	x	
3.	Quality Improvement	x	
4.	Documents and Records	x	
5.	Work Processes	x	
6.	Design		
7.	Procurement		
8.	Inspection and Acceptance Testing		
9.	Management Assessment	x	
10.	Independent Assessment	x	

3 Quality Assurance Planning and Implementation Review

For each QA criterion checked on the Quality Assurance Plan Checklist, read the appropriate discussion in the corresponding section of the Division's *QA Plan*. Pay particular attention to your requirements as a PI for the activity in question. Then do the following:

- For each QA criterion that applies to your activity, mark (with an "x") the appropriate box on the Quality Assurance Planning and Implementation Review to indicate one of the following:

  - The ER Division's *QA Plan* specifies adequate control.

  - Another existing document specifies adequate control. (Name that document on an appended page.)

  - A project-specific amendment to the ER Division's *QA Plan* is required. (Define the amendment[s] on an appended page.)

- If QA criterion 6, 7, or 8 does not apply to your activity (as established in the Quality Assurance Plan Checklist), mark (with "NA") all three columns for that criterion on the Quality Assurance Planning and Implementation Review.

Quality Assurance Planning and Implementation Review

For each of the ten QA criteria below, do the following:

- Mark (with an "x") the "ER Division Plan" column if the *Environmental Research Division Quality Assurance Plan* specifies adequate control.
- Mark (with an "x") the "Other Document" column if another existing document (aside from the *Environmental Research Division Quality Assurance Plan*) specifies adequate control. Identify the existing document on an appended page.
- Mark (with an "x") the "Amendment" column if project-specific amendment(s) must be prepared to specify adequate control. Define the new amendment(s) on an appended page.
- For QA criterion 6, 7, or 8, mark all three columns (with "NA") if the criterion does not apply to your activity (as established in the Quality Assurance Plan Checklist).

Quality Assurance Criterion	ER Division Plan	Other Document	Amendment
1. Program			
2. Personnel Training and Qualifications			
3. Quality Improvement			
4. Documents and Records			
5. Work Processes			
6. Design			
7. Procurement			
8. Inspection and Acceptance Testing			
9. Management Assessment			
10. Independent Assessment			

4 Quality Assurance Plan Summary and Certification

The Quality Assurance Plan Summary and certification summarizes and documents the results of the previous two forms.

If the completed Quality Assurance Planning and Implementation Review indicates that the ER Division's *QA Plan* provides controls adequate to ensure satisfactory QA for your activity, sign Section 1 of the Quality Assurance Plan Summary and Certification.

If the completed Quality Assurance Planning and Implementation Review indicates, for any QA criterion, that an existing document other than the ER Division's *QA Plan* is required to specify adequate control for your activity or that amendment(s) to the ER Division *QA Plan* must be prepared, sign Section 2 of the Quality Assurance Plan Summary and Certification. The QA plan for your activity is then the Division's *QA Plan* plus the other existing document or the new QA amendment(s) addressing the criterion (criteria) for which control is not adequately specified by the Division's *QA Plan*. The PI has the responsibility to define and document these additional QA requirements.

Quality Assurance Plan Summary and Certification

1. My review of the program requirements has revealed no quality-affecting activities or risks affecting compliance, health, safety, cost, or schedule that require a unique QA plan. The use of existing procedures described in the *Environmental Research Division Quality Assurance Plan* will provide the controls necessary to ensure satisfactory results.

Principal Investigator _____ Date _____

2. My review of the program requirements has revealed that certain quality-affecting activities require controls that are not contained in the *Environmental Research Division Quality Assurance Plan.* These additional requirements are identified and summarized on the attached sheet. I have checked the appropriate line below.

   _____ Another existing document provides the needed control. The title of that document is:

   _____

   _____ It will be necessary to prepare detailed, written *QA Plan* amendment(s) for the proposed activity.

Principal Investigator _____ Date _____